



11-10-08

11/08 AF
J

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s): BURGIO et al. Group Art Unit: 1612
Serial No.: 10/626,142 Examiner: Darryl C. Sutton
Filed: 24 July 2003 Docket No.: 58359US003
Confirmation No.:9324
Title: DENTAL WHITENING COMPOSITIONS AND METHODS

Mail Stop Appeal Brief - Patents

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

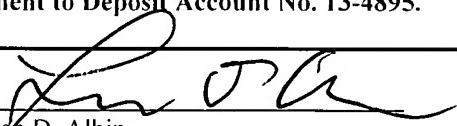
We are transmitting the following documents along with this transmittal sheet:

An itemized return postcard.

An Appeal Brief (17 pgs); Claims Appendix (22 pgs); Evidence Appendix (1 page); Related Proceedings Appendix (1 page); Cited Authorities and Documents Appendix (1 page); Copies of 2 documents cited on Cited Authorities and Documents Appendix (6 pgs). Please charge Deposit Account No. 13-4895 in the amount of \$540, for the required Appeal Brief filing fee.

Please consider this a PETITION FOR EXTENSION OF TIME for a sufficient number of months to enter these papers and please charge any additional fees or credit overpayment to Deposit Account No. 13-4895.

MUETING, RAASCH & GEBHARDT, P.A.
Customer Number: 26813

By: 
Name: Loren D. Albin
Reg. No.: 37,763
Direct Dial: 612-305-1225
Facsimile: 612-305-1228

CERTIFICATE UNDER 37 CFR §1.10::

"Express Mail" mailing label number: EM 118968305 US

Date of Deposit: November 7th, 2008

I hereby certify that the Transmittal Letter and the paper(s) and/or fee(s), as described hereinabove, are being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR §1.10 on the date indicated above and is addressed to: **Mail Stop Appeal Brief - Patents** Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

By: Dani Moroz
Name: Dani Moroz

(LARGE ENTITY TRANSMITTAL UNDER RULE 1.10)



PATENT
Docket No. 58359US003

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appellant(s):	BURGIO et al.)	Group Art Unit:	1612
Serial No.:	10/626,142)	Examiner:	Darryl C. Sutton
Confirmation No.:	9324)		
Filed:	24 July 2003)		
For:	DENTAL WHITENING COMPOSITIONS AND METHODS			

APPEAL BRIEF

Commissioner for Patents
Mail Stop - Appeal Brief - Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

This Brief is presented in support of the Appeal filed 8 September 2008, from the final rejection of claims 1-3, 5-17, 19-25, 27-32, 34-43, and 45-80 of the above identified application under 37 C.F.R. §§ 1.113 and 1.191. This Brief is being submitted as set forth in 37 C.F.R. § 41.37. Please charge Deposit Account No. 13-4895 the fee for filing this Brief under 37 C.F.R. § 41.20(b)(2).

I. REAL PARTY IN INTEREST

The real party in interest of the above-identified patent application is the assignee, 3M Innovative Properties Company. 3M Innovative Properties Company is a wholly-owned subsidiary of 3M Company.

II. RELATED APPEALS AND INTERFERENCES

There are no appeals or interferences known to Appellants' Representatives which would directly affect, be directly affected by, or have a bearing on the Board's decision in the pending appeal.

11/12/2008 MBELETE1 00000005 134895 10626142
01 FC:1402 540.00 DA

III. STATUS OF CLAIMS

The pending claims, claims 1-3, 5-17, 19-25, 27-32, 34-43, and 45-80, all stand rejected and are all subject to this Appeal. A clean copy of the rejected claims is included in the Claims Appendix pursuant to M.P.E.P. § 1205.02 and 37 C.F.R. § 41.37(c)(1)(viii).

IV. STATUS OF AMENDMENTS

A Response under 37 C.F.R. § 1.116 was filed on 6 August 2008. The Response did not include any amendments to the claims. The Advisory Action mailed 2 September 2008 indicated that the arguments in the Response under 37 C.F.R. § 1.116 had been considered, but did not place the application in condition for allowance.

V. SUMMARY OF CLAIMED SUBJECT MATTER

Claim 1 recites a dental whitening composition (e.g., page 4, line 16 to page 5, line 10) suitable for coating oral surfaces (e.g., page 20, line 9 to page 22, line 11). The dental whitening composition includes a tooth whitening agent (e.g., page 5, lines 12-28); and a polymer (e.g., page 5, line 30 to page 6, line 18). The polymer includes a repeating unit (e.g., page 3, lines 25-28) including a polar or polarizable group (e.g., page 8, line 28 to page 11, line 18); and a repeating unit including a fluoride releasing group (e.g., page 11, lines 20-27), with the proviso that the polymer does not include pendant ethylenically unsaturated moieties (e.g., page 6, lines 15-16), wherein the repeating unit including the polar or polarizable group is different than the repeating unit including the fluoride releasing group (e.g., page 6, lines 16-18), and wherein the composition includes about 0.05% by weight to about 50% by weight of the tooth whitening agent, based on the total weight of the tooth whitening agent and the polymer (e.g., page 5, lines 22-28).

Claim 8 recites a dental whitening composition (e.g., page 4, line 16 to page 5, line 10) suitable for coating oral surfaces (e.g., page 20, line 9 to page 22, line 11). The dental whitening composition includes greater than 10% by weight (e.g., page 6, line 20) of a tooth whitening

agent (e.g., page 5, lines 12-28), based on the total weight of the dental whitening composition; and a polymer (e.g., page 5, line 30 to page 6, line 11; and page 6, lines 19-25). The polymer includes a repeating unit (e.g., page 3, lines 25-28) including a polar or polarizable group (e.g., page 8, line 28 to page 11, line 18); and a repeating unit including a fluoride releasing group (e.g., page 11, lines 20-27), wherein the repeating unit including the polar or polarizable group is different than the repeating unit including the fluoride releasing group (e.g., page 6, lines 23-25).

Claim 15 recites a dental whitening composition (e.g., page 4, line 16 to page 5, line 10) suitable for coating oral surfaces (e.g., page 20, line 9 to page 22, line 11). The dental whitening composition includes a tooth whitening agent (e.g., page 5, lines 12-28); and a polymer (e.g., page 5, line 30 to page 6, line 11; and page 6, lines 26-32). The polymer includes a repeating unit (e.g., page 3, lines 25-28) including a polar or polarizable group (e.g., page 8, line 28 to page 11, line 18); and a repeating unit including a fluoride releasing group (e.g., page 11, lines 20-27), with the proviso that the dental whitening composition does not include hydrogen peroxide (e.g., page 6, lines 29-30), wherein the repeating unit including the polar or polarizable group is different than the repeating unit including the fluoride releasing group (e.g., page 6, lines 31-32), and wherein the composition includes about 0.05% by weight to about 50% by weight of the tooth whitening agent, based on the total weight of the tooth whitening agent and the polymer (e.g., page 5, lines 22-28).

Claim 23 recites a dental whitening composition (e.g., page 4, line 16 to page 5, line 10) suitable for coating oral surfaces (e.g., page 20, line 9 to page 22, line 11). The dental whitening composition includes a tooth whitening agent (e.g., page 5, lines 12-28); and a polymer (e.g., page 5, line 30 to page 6, line 11; and page 7, lines 1-6). The polymer includes a repeating unit (e.g., page 3, lines 25-28) including a polar or polarizable group (e.g., page 8, line 28 to page 11, line 18); and a repeating unit including a fluoride releasing group including tetrafluoroborate anions (e.g., page 11, lines 20-27), wherein the repeating unit including the polar or polarizable group is different than the repeating unit including the fluoride releasing group (e.g., page 7, lines 5-6), and wherein the composition includes about 0.05% by weight to about 50% by weight

of the tooth whitening agent, based on the total weight of the tooth whitening agent and the polymer (e.g., page 5, lines 22-28).

Claim 30 recites a dental whitening composition (e.g., page 4, line 16 to page 5, line 10) suitable for coating oral surfaces (e.g., page 20, line 9 to page 22, line 11). The dental whitening composition includes a tooth whitening agent (e.g., page 5, lines 12-28); and a polymer (e.g., page 5, line 30 to page 6, line 11; and page 7, lines 7-18). The polymer includes a repeating unit (e.g., page 3, lines 25-28) including a polar or polarizable group (e.g., page 8, line 28 to page 11, line 18); a repeating unit including a fluoride releasing group (e.g., page 11, lines 20-27); and a repeating unit including a group selected from the group consisting of a hydrophobic hydrocarbon group (e.g., page 11, line 29 to page 12, line 13), a graft polysiloxane chain (e.g., page 13, lines 1-19), a hydrophobic fluorine-containing group (e.g., page 12, lines 15-30), and combinations thereof (e.g., page 6, lines 1-5), with the proviso that the polymer does not include pendant ethylenically unsaturated moieties (e.g., page 7, lines 12-13), wherein the repeating unit including the polar or polarizable group is different than the repeating unit including the fluoride releasing group (e.g., page 6, lines 16-18), and wherein the composition includes about 0.05% by weight to about 50% by weight of the tooth whitening agent, based on the total weight of the tooth whitening agent and the polymer (e.g., page 5, lines 22-28).

Claim 37 recites a dental whitening composition (e.g., page 4, line 16 to page 5, line 10) suitable for coating oral surfaces (e.g., page 20, line 9 to page 22, line 11). The dental whitening composition includes greater than 10% by weight (e.g., page 7, line 20) of a tooth whitening agent (e.g., page 5, lines 12-28), based on the total weight of the dental whitening composition; and a polymer (e.g., page 5, line 30 to page 6, line 11; and page 7, lines 19-31). The polymer includes a repeating unit (e.g., page 3, lines 25-28) including a polar or polarizable group (e.g., page 8, line 28 to page 11, line 18); a repeating unit including a fluoride releasing group (e.g., page 11, lines 20-27); and a repeating unit including a group selected from the group consisting of a hydrophobic hydrocarbon group (e.g., page 11, line 29 to page 12, line 13), a graft polysiloxane chain (e.g., page 13, lines 1-19), a hydrophobic fluorine-containing group (e.g., page 12, lines 15-30), and combinations thereof (e.g., page 6, lines 1-5), wherein the repeating

unit including the polar or polarizable group is different than the repeating unit including the fluoride releasing group (e.g., page 6, lines 23-25).

Claim 41 recites a dental whitening composition (e.g., page 4, line 16 to page 5, line 10) suitable for coating oral surfaces (e.g., page 20, line 9 to page 22, line 11). The dental whitening composition includes a tooth whitening agent (e.g., page 5, lines 12-28); and a polymer (e.g., page 5, line 30 to page 6, line 11; and page 8, lines 1-13). The polymer includes a repeating unit (e.g., page 3, lines 25-28) including a polar or polarizable group (e.g., page 8, line 28 to page 11, line 18); a repeating unit including a fluoride releasing group (e.g., page 11, lines 20-27); and a repeating unit including a group selected from the group consisting of a hydrophobic hydrocarbon group (e.g., page 11, line 29 to page 12, line 13), a graft polysiloxane chain (e.g., page 13, lines 1-19), a hydrophobic fluorine-containing group (e.g., page 12, lines 15-30), and combinations thereof (e.g., page 6, lines 1-5), wherein the repeating unit including the polar or polarizable group is different than the repeating unit including the fluoride releasing group (e.g., page 6, lines 31-32), and with the proviso that the dental whitening composition does not include hydrogen peroxide (e.g., page 8, lines 6-7), and wherein the composition includes about 0.05% by weight to about 50% by weight of the tooth whitening agent, based on the total weight of the tooth whitening agent and the polymer (e.g., page 5, lines 22-28).

Claim 46 recites a coating on hard tissue surfaces or surfaces of the oral environment (e.g., page 20, line 20 to page 22, line 11). The coating includes a tooth whitening agent (e.g., page 5, lines 12-28); and a polymer (e.g., page 5, line 30 to page 6, line 18). The polymer includes a repeating unit (e.g., page 3, lines 25-28) including a polar or polarizable group (e.g., page 8, line 28 to page 11, line 18); and a repeating unit including a fluoride releasing group (e.g., page 11, lines 20-27), with the proviso that the polymer does not include pendant ethylenically unsaturated moieties (e.g., page 6, lines 15-16), wherein the repeating unit including the polar or polarizable group is different than the repeating unit including the fluoride releasing group (e.g., page 6, lines 16-18), and wherein the coating includes about 0.05% by weight to about 50% by weight of the tooth whitening agent, based on the total weight of the tooth whitening agent and the polymer (e.g., page 5, lines 22-28).

Claim 47 recites a coating on hard tissue surfaces or surfaces of the oral environment (e.g., page 20, line 20 to page 22, line 11). The coating includes greater than 10% by weight (e.g., page 6, line 20) of a tooth whitening agent (e.g., page 5, lines 12-28), based on the total weight of the coating; and a polymer (e.g., page 5, line 30 to page 6, line 11; and page 6, lines 19-25). The polymer includes a repeating unit (e.g., page 3, lines 25-28) including a polar or polarizable group (e.g., page 8, line 28 to page 11, line 18); and a repeating unit including a fluoride releasing group (e.g., page 11, lines 20-27), wherein the repeating unit including the polar or polarizable group is different than the repeating unit including the fluoride releasing group (e.g., page 6, lines 23-25).

Claim 48 recites a coating on hard tissue surfaces or surfaces of the oral environment (e.g., page 20, line 20 to page 22, line 11). The coating includes a tooth whitening agent (e.g., page 5, lines 12-28); and a polymer (e.g., page 5, line 30 to page 6, line 11; and page 6, lines 26-32). The polymer includes a repeating unit (e.g., page 3, lines 25-28) including a polar or polarizable group (e.g., page 8, line 28 to page 11, line 18); and a repeating unit including a fluoride releasing group (e.g., page 11, lines 20-27), wherein the repeating unit including the polar or polarizable group is different than the repeating unit including the fluoride releasing group (e.g., page 6, lines 31-32), and with the proviso that the dental whitening composition does not include hydrogen peroxide (e.g., page 6, lines 29-30), and wherein the coating includes about 0.05% by weight to about 50% by weight of the tooth whitening agent, based on the total weight of the tooth whitening agent and the polymer (e.g., page 5, lines 22-28).

Claim 49 recites a coating on hard tissue surfaces or surfaces of the oral environment (e.g., page 20, line 20 to page 22, line 11). The coating includes a tooth whitening agent (e.g., page 5, lines 12-28); and a polymer (e.g., page 5, line 30 to page 6, line 11; and page 7, lines 1-6). The polymer includes a repeating unit (e.g., page 3, lines 25-28) including a polar or polarizable group (e.g., page 8, line 28 to page 11, line 18); and a repeating unit including a fluoride releasing group including tetrafluoroborate anions (e.g., page 11, lines 20-27), wherein the repeating unit including the polar or polarizable group is different than the repeating unit including the fluoride releasing group (e.g., page 7, lines 5-6), and wherein the coating includes

about 0.05% by weight to about 50% by weight of the tooth whitening agent, based on the total weight of the tooth whitening agent and the polymer (e.g., page 5, lines 22-28).

Claim 50 recites a coating on hard tissue surfaces or surfaces of the oral environment (e.g., page 20, line 20 to page 22, line 11). The coating includes a tooth whitening agent (e.g., page 5, lines 12-28); and a polymer (e.g., page 5, line 30 to page 6, line 11; and page 7, lines 7-18). The polymer includes a repeating unit (e.g., page 3, lines 25-28) including a polar or polarizable group (e.g., page 8, line 28 to page 11, line 18); a repeating unit including a fluoride releasing group (e.g., page 11, lines 20-27); and a repeating unit including a group selected from the group consisting of a hydrophobic hydrocarbon group (e.g., page 11, line 29 to page 12, line 13), a graft polysiloxane chain (e.g., page 13, lines 1-19), a hydrophobic fluorine-containing group (e.g., page 12, lines 15-30), and combinations thereof (e.g., page 6, lines 1-5), with the proviso that the polymer does not include pendant ethylenically unsaturated moieties (e.g., page 7, lines 12-13), wherein the repeating unit including the polar or polarizable group is different than the repeating unit including the fluoride releasing group (e.g., page 6, lines 16-18), and wherein the coating includes about 0.05% by weight to about 50% by weight of the tooth whitening agent, based on the total weight of the tooth whitening agent and the polymer (e.g., page 5, lines 22-28).

Claim 51 recites a coating on hard tissue surfaces or surfaces of the oral environment (e.g., page 20, line 20 to page 22, line 11). The coating includes greater than 10% by weight (e.g., page 7, line 20) of a tooth whitening agent (e.g., page 5, lines 12-28), based on the total weight of the coating; and a polymer (e.g., page 5, line 30 to page 6, line 11; and page 7, lines 19-31). The polymer includes a repeating unit (e.g., page 3, lines 25-28) including a polar or polarizable group (e.g., page 8, line 28 to page 11, line 18); a repeating unit including a fluoride releasing group (e.g., page 11, lines 20-27); and a repeating unit including a group selected from the group consisting of a hydrophobic hydrocarbon group (e.g., page 11, line 29 to page 12, line 13), a graft polysiloxane chain (e.g., page 13, lines 1-19), a hydrophobic fluorine-containing group (e.g., page 12, lines 15-30), and combinations thereof (e.g., page 6, lines 1-5), wherein the

repeating unit including the polar or polarizable group is different than the repeating unit including the fluoride releasing group (e.g., page 6, lines 23-25).

Claim 52 recites a coating on hard tissue surfaces or surfaces of the oral environment (e.g., page 20, line 20 to page 22, line 11). The coating includes a tooth whitening agent (e.g., page 5, lines 12-28); and a polymer (e.g., page 5, line 30 to page 6, line 11; and page 8, lines 1-13). The polymer includes a repeating unit (e.g., page 3, lines 25-28) including a polar or polarizable group (e.g., page 8, line 28 to page 11, line 18); a repeating unit including a fluoride releasing group (e.g., page 11, lines 20-27); and a repeating unit including a group selected from the group consisting of a hydrophobic hydrocarbon group (e.g., page 11, line 29 to page 12, line 13), a graft polysiloxane chain (e.g., page 13, lines 1-19), a hydrophobic fluorine-containing group (e.g., page 12, lines 15-30), and combinations thereof (e.g., page 6, lines 1-5), wherein the repeating unit including the polar or polarizable group is different than the repeating unit including the fluoride releasing group (e.g., page 6, lines 31-32), and with the proviso that the dental whitening composition does not include hydrogen peroxide (e.g., page 8, lines 6-7), and wherein the coating includes about 0.05% by weight to about 50% by weight of the tooth whitening agent, based on the total weight of the tooth whitening agent and the polymer (e.g., page 5, lines 22-28).

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

A. Whether the Examiner has established a *prima facie* case of obviousness under 35 U.S.C. § 103(a) for claims 1-3, 5, 8-11, 14-17, 19, 22, 30-32, 34, 36-43, 45-64, and 69-80 being unpatentable over Mitra et al. (U.S. Patent No. 5,888,491) in view of Majeti et al. (U.S. Patent No. 7,025,950).

B. Whether the Examiner has established a *prima facie* case of obviousness under 35 U.S.C. § 103(a) for claims 6-7, 12-13, 20-21, 23-25, 27-29, and 65-68 being unpatentable over Mitra et al. (U.S. Patent No. 5,888,491) in view of Majeti et al. (U.S. Patent No. 7,025,950), the combination being taken in further view of Aasen et al. (U.S. Patent No. 4,871,786).

C. Whether the Examiner has established a *prima facie* case of obviousness under 35 U.S.C. § 103(a) for claims 30-32, 34-35, 37-43, 45, 50-52, and 60-68 being unpatentable over Rozzi et al. (U.S. Patent No. 5,607,663) in view of Majeti et al. (U.S. Patent No. 7,025,950).

VII. ARGUMENT

A. The Examiner has not established a *prima facie* case of obviousness under 35 U.S.C. § 103(a) for claims 1-3, 5, 8-11, 14-17, 19, 22, 30-32, 34, 36-43, 45-64, and 69-80 being unpatentable over Mitra et al. (U.S. Patent No. 5,888,491) in view of Majeti et al. (U.S. Patent No. 7,025,950).

"*The examiner bears the initial burden of factually supporting* any *prima facie* conclusion of obviousness." M.P.E.P. § 2142 (emphasis added). "A prior art reference must be considered in its entirety, i.e., as a whole." M.P.E.P. § 2141.02(VI) (emphasis in original).

Appellants respectfully submit that the Examiner has not satisfied the initial burden of factually supporting the Examiner's conclusion of obviousness, for at least the reason that the Examiner's factual support is clearly erroneous, as discussed herein below.

To support the rejection, Appellants respectfully submit that the Examiner has improperly relied on Mitra et al. for disclosing a polymer that includes, among other things, a repeating unit including a polar or polarizable group and a repeating unit including a fluoride releasing group, *wherein the repeating unit including the polar or polarizable group is different than the repeating unit including the fluoride releasing group* (e.g., independent claims 1, 8, 15, 30, 37, 41, and 46-52). Specifically, the Examiner alleged that Mitra et al. disclose that "***Unit B monomers include branched or cyclic alcohols***, i.e. compounds with a polar or polarizable hydroxy group (column 5, lines 16-20)." (Office Action dated 6 June 2008, page 3, lines 12-14; emphasis added.) Appellants earnestly disagree, and respectfully submit that the Examiner's allegation is clear error, as discussed herein below.

Appellants respectfully submit that the Examiner has improperly parsed the language of Mitra et al. In actuality, the passage of Mitra et al. cited by the Examiner reads as follows:

"Examples of unit B monomers include the lower to intermediate methacrylic acid esters of 1-12 carbon straight, branched or cyclic alcohols." (Mitra et al., column 5, lines 16-18.) Appellants respectfully submit that it would be abundantly clear to one of skill in the art, in view of the disclosure of Mitra et al. as a whole, that the recited passage indicates that unit B monomers can be methacrylic acid esters of 1-12 carbon straight alcohols, methacrylic acid esters of 1-12 carbon branched alcohols, or methacrylic acid esters of 1-12 carbon cyclic alcohols. Appellants note that *carboxylic acid esters of alcohols are not alcohols (i.e., the polar or polarizable hydroxy group of the alcohol that reacts to form the ester is no longer present in the resultant carboxylic acid ester)*. Further, Appellants have been unable to locate any support in Mitra et al. for the Examiner's allegation that unit B monomers can be branched or cyclic alcohols. Finally, it is unclear to Appellants' Representatives how a branched or cyclic alcohol, without more, could even be a monomer. For example, Mitra et al. recite that "[t]he unit B is derived from acrylate or methacrylate or other vinyl polymerizable starting monomers" (column 5, lines 11-12).

Even further, the Examiner admitted that "the second repeating unit cited by the examiner, 'branched or cyclic alcohols' was in fact used to produce the repeating unit and is not a monomer on its own. The examiner agrees." (Advisory Action dated 2 September 2008, Continuation Sheet, lines 3-4.) Thus, Appellants respectfully note that the record is abundantly clear, as admitted by the Examiner, that the Examiner's reliance on the alleged disclosure by Mitra et al. of a branched or cyclic alcohol to meet the language of a repeating unit including a polar or polarizable group is misfounded, for at least the reasons that (1) Mitra et al. disclose branched or cyclic alcohols not as monomers, but as precursors to carboxylic acid esters, and (2) the polar or polarizable hydroxy group of the alcohol that reacts to form the ester is no longer present in the resultant carboxylic acid ester.

Nonetheless, the Examiner asserted that:

Mitra et al. which teaches that the monomer of Unit A is derived from vinylic monomers such as acrylates, methacrylates,

crotonates, itaconates and the like (column 3, lines 44-47). Unit B is derived from acrylate or methacrylate or "other" vinyl polymerizable starting monomers, including styrene, vinyl chloride, vinylidene chloride, acryloyl monomers and the like (column 5, lines 10-20). Both unit A and unit B have several possible monomers which would produce different repeating groups, i.e. Unit A with an acrylate monomer and Unit B with a styrene monomer. (Advisory Action dated 2 September 2008, Continuation Sheet, lines 4-8.)

Without taking a position on the accuracy of the Examiner's above-quoted assertion, Appellants respectfully submit that in no manner does the assertion even factually support an allegation that Mitra et al. disclose a repeating unit including a polar or polarizable group.

For at least this reason, the Examiner has not met the initial burden of factually supporting a *prima facie* conclusion of obviousness for claims 1-3, 5, 8-11, 14-17, 19, 22, 30-32, 34, 36-43, 45-64, and 69-80 being unpatentable over Mitra et al. in view of Majeti et al.

Review and reversal of the rejection under 35 U.S.C. § 103(a) by the Board are respectfully requested.

B. The Examiner has not established a *prima facie* case of obviousness under 35 U.S.C. § 103(a) for claims 6-7, 12-13, 20-21, 23-25, 27-29, and 65-68 being unpatentable over Mitra et al. (U.S. Patent No. 5,888,491) in view of Majeti et al. (U.S. Patent No. 7,025,950), the combination being taken in further view of Aasen et al. (U.S. Patent No. 4,871,786).

"*The examiner bears the initial burden of factually supporting any *prima facie* conclusion of obviousness.*" M.P.E.P. § 2142 (emphasis added). "A prior art reference must be considered in its entirety, i.e., as a whole." M.P.E.P. § 2141.02(VI) (emphasis in original).

Appellants respectfully submit that the Examiner has not satisfied the initial burden of factually supporting the Examiner's conclusion of obviousness, for at least the reason that the Examiner's factual support is clearly erroneous, as discussed herein below.

To support the rejection, Appellants respectfully submit that the Examiner has improperly relied on Mitra et al. for disclosing a polymer that includes, among other things, a repeating unit including a polar or polarizable group and a repeating unit including a fluoride releasing group, *wherein the repeating unit including the polar or polarizable group is different than the repeating unit including the fluoride releasing group* (e.g., independent claims 1, 8, 15, and 23, which are either rejected or have rejected claims depending therefrom). Specifically, the Examiner alleged that Mitra et al. disclose that "**Unit B monomers include branched or cyclic alcohols**, i.e. compounds with a polar or polarizable hydroxy group (column 5, lines 16-20):" (Office Action dated 6 June 2008, page 3, lines 12-14; emphasis added.) Appellants earnestly disagree, and respectfully submit that the Examiner's allegation is clear error, as discussed herein below.

Appellants respectfully submit that the Examiner has improperly parsed the language of Mitra et al. In actuality, the passage of Mitra et al. cited by the Examiner reads as follows: "Examples of unit B monomers include the lower to intermediate methacrylic acid esters of 1-12 carbon straight, branched or cyclic alcohols." (Mitra et al., column 5, lines 16-18.) Appellants respectfully submit that it would be abundantly clear to one of skill in the art, in view of the disclosure of Mitra et al. as a whole, that the recited passage indicates that unit B monomers can be methacrylic acid esters of 1-12 carbon straight alcohols, methacrylic acid esters of 1-12 carbon branched alcohols, or methacrylic acid esters of 1-12 carbon cyclic alcohols. Appellants note that *carboxylic acid esters of alcohols are not alcohols (i.e., the polar or polarizable hydroxy group of the alcohol that reacts to form the ester is no longer present in the resultant carboxylic acid ester)*. Further, Appellants have been unable to locate any support in Mitra et al. for the Examiner's allegation that unit B monomers can be branched or cyclic alcohols. Finally, it is unclear to Appellants' Representatives how a branched or cyclic alcohol, without more, could even be a monomer. For example, Mitra et al. recite that "[t]he unit B is derived from acrylate or methacrylate or other vinyl polymerizable starting monomers" (column 5, lines 11-12).

Even further, the Examiner admitted that "the second repeating unit cited by the examiner, 'branched or cyclic alcohols' was in fact used to produce the repeating unit and is not a monomer on its own. The examiner agrees." (Advisory Action dated 2 September 2008, Continuation Sheet, lines 3-4.) Thus, Appellants respectfully note that the record is abundantly clear, as admitted by the Examiner, that the Examiner's reliance on the alleged disclosure by Mitra et al. of a branched or cyclic alcohol to meet the language of a repeating unit including a polar or polarizable group is misfounded, for at least the reasons that (1) Mitra et al. disclose branched or cyclic alcohols not as monomers, but as precursors to carboxylic acid esters, and (2) the polar or polarizable hydroxy group of the alcohol that reacts to form the ester is no longer present in the resultant carboxylic acid ester.

Nonetheless, the Examiner asserted that:

Mitra et al. which teaches that the monomer of Unit A is derived from vinylic monomers such as acrylates, methacrylates, crotonates, itaconates and the like (column 3, lines 44-47). Unit B is derived from acrylate or methacrylate or "other" vinyl polymerizable starting monomers, including styrene, vinyl chloride, vinylidene chloride, acryloyl monomers and the like (column 5, lines 10-20). Both unit A and unit B have several possible monomers which would produce different repeating groups, i.e. Unit A with an acrylate monomer and Unit B with a styrene monomer. (Advisory Action dated 2 September 2008, Continuation Sheet, lines 4-8.)

Without taking a position on the accuracy of the Examiner's above-quoted assertion, Appellants respectfully submit that in no manner does the assertion even factually support an allegation that Mitra et al. disclose a repeating unit including a polar or polarizable group.

For at least this reason, the Examiner has not met the initial burden of factually supporting a *prima facie* conclusion of obviousness for claims 6-7, 12-13, 20-21, 23-25, 27-29, and 65-68 being unpatentable over Mitra et al. in view of Majeti et al., the combination being taken in further view of Aasen et al.

Review and reversal of the rejection under 35 U.S.C. § 103(a) by the Board are respectfully requested.

C. The Examiner has not established a *prima facie* case of obviousness under 35 U.S.C. § 103(a) for claims 30-32, 34-35, 37-43, 45, 50-52, and 60-68 being unpatentable over Rozzi et al. (U.S. Patent No. 5,607,663) in view of Majeti et al. (U.S. Patent No. 7,025,950).

"*The examiner bears the initial burden of factually supporting any *prima facie* conclusion of obviousness.*" M.P.E.P. § 2142 (emphasis added). "A prior art reference must be considered in its entirety, i.e., as a whole." M.P.E.P. § 2141.02(VI) (emphasis in original).

Appellants respectfully submit that the Examiner has not satisfied the initial burden of factually supporting the Examiner's conclusion of obviousness, for at least the reason that the Examiner's factual support is clearly erroneous, as discussed herein below.

To support the rejection, Appellants respectfully submit that the Examiner has improperly relied on Rozzi et al. for disclosing a polymer that includes, among other things, a repeating unit including a polar or polarizable group and a repeating unit including a fluoride releasing group, *wherein the repeating unit including the polar or polarizable group is different than the repeating unit including the fluoride releasing group* (e.g., independent claims 8, 15, 23, 30, 37, 41, and 50-52, each of which is rejected and/or has rejected claims depending therefrom). Specifically, the Examiner alleged that Rozzi et al. disclose that "Unit B monomers include branched or cyclic alcohols, i.e. compound with a polar or polarizable hydroxy group (column 4, lines 35-40)." (Office Action dated 6 June 2008, page 4, lines 16-18.) Appellants earnestly disagree, and respectfully submit that the Examiner's allegation is clear error, as discussed herein below.

Appellants respectfully submit that the Examiner has improperly parsed the language of Rozzi et al. In actuality, the passage of Rozzi et al. cited by the Examiner reads as follows: "Examples of unit B monomers include the lower to intermediate methacrylic acid esters of 1-12 carbon straight, branched or cyclic alcohols." (Rozzi et al., column 4, lines 35-37.) Appellants

respectfully submit that it would be abundantly clear to one of skill in the art, in view of the disclosure of Rozzi et al. as a whole, that the recited passage indicates that unit B monomers can be methacrylic acid esters of 1-12 carbon straight alcohols, methacrylic acid esters of 1-12 carbon branched alcohols, or methacrylic acid esters of 1-12 carbon cyclic alcohols. Appellants note that *carboxylic acid esters of alcohols are not alcohols (i.e., the polar or polarizable hydroxy group of the alcohol that reacts to form the ester is no longer present in the resultant carboxylic acid ester)*. Further, Appellants have been unable to locate any support in Rozzi et al. for the Examiner's allegation that unit B monomers can be branched or cyclic alcohols. Finally, it is unclear to Appellants' Representatives how a branched or cyclic alcohol, without more, could even be a monomer. For example, Rozzi et al. recite that "[t]he unit B is derived from acrylate or methacrylate or other vinyl polymerizable starting monomers" (column 4, lines 30-31).

Even further, the Examiner admitted that "the second repeating unit cited by the examiner, 'branched or cyclic alcohols' was in fact used to produce the repeating unit and is not a monomer on its own. The examiner agrees." (Advisory Action dated 2 September 2008, Continuation Sheet, lines 3-4.) Thus, Appellants respectfully note that the record is abundantly clear, as admitted by the Examiner, that the Examiner's reliance on the alleged disclosure by Rozzi et al. of a branched or cyclic alcohol to meet the language of a repeating unit including a polar or polarizable group is misfounded, for at least the reasons that (1) Rozzi et al. disclose branched or cyclic alcohols not as monomers, but as precursors to carboxylic acid esters, and (2) the polar or polarizable hydroxy group of the alcohol that reacts to form the ester is no longer present in the resultant carboxylic acid ester.

Nonetheless, the Examiner asserted that:

Rozzi et al. which teaches that the monomer of Unit A is derived from vinylic monomers such as acrylates, methacrylates, crotonates, itaconates and the like (column 2, lines 64-66). Unit B is derived from acrylate or methacrylate or "other" vinyl polymerizable starting monomers, including styrene, vinyl

chloride, vinylidene chloride, acryloyl monomers and the like (column 4, lines 30-40). Both unit A and unit B have several possible monomers which would produce different repeating groups, i.e. Unit A with an acrylate monomer and Unit B with a styrene monomer. (Advisory Action dated 2 September 2008, Continuation Sheet, lines 8-13.)

Without taking a position on the accuracy of the Examiner's above-quoted assertion, Appellants respectfully submit that in no manner does the assertion even factually support an allegation that Rozzi et al. disclose a repeating unit including a polar or polarizable group.

For at least this reason, the Examiner has not met the initial burden of factually supporting a *prima facie* conclusion of obviousness for claims 30-32, 34-35, 37-43, 45, 50-52, and 60-68 being unpatentable over Rozzi et al. in view of Majeti et al.

Review and reversal of the rejection under 35 U.S.C. § 103(a) by the Board are respectfully requested.

Appeal Brief
Serial No.: 10/626,142
Confirmation No.: 9324
Filed: 24 July 2003
For: DENTAL WHITENING COMPOSITIONS AND METHODS

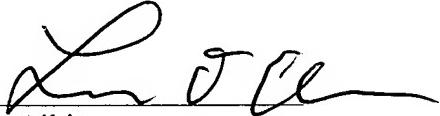
Page 17 of 17

VIII. SUMMARY

For the foregoing reasons, Appellants respectfully request that the Board review and reverse the rejection of claims 1-3, 5-17, 19-25, 27-32, 34-43, and 45-80 as discussed herein and that notification of the allowance of these claims be issued.

Respectfully submitted
By
Mueting, Raasch & Gebhardt, P.A.
P.O. Box 581336
Minneapolis, MN 55458-1336
(612)305-1220

Date: November 7, 2008

By: 
Loren D. Albin
Reg. No. 37,763
Direct Dial: (612)305-1225

CERTIFICATE UNDER 37 CFR § 1.10:

"Express Mail" mailing label number: EM 118968305 US

Date of Deposit: November 7, 2008

The undersigned hereby certifies that this paper is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR § 1.10 on the date indicated above and is addressed to **Mail Stop Appeal Brief - Patents**, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

By: Dani Meroz
Name: Dani Meroz



CLAIMS APPENDIX

Serial No. 10/626,142

Docket No. 58359US003

1. A dental whitening composition suitable for coating oral surfaces comprising:
 - a tooth whitening agent; and
 - a polymer comprising:
 - a repeating unit comprising a polar or polarizable group; and
 - a repeating unit comprising a fluoride releasing group,

with the proviso that the polymer does not include pendant ethylenically unsaturated moieties,

wherein the repeating unit comprising the polar or polarizable group is different than the repeating unit comprising the fluoride releasing group, and

wherein the composition comprises about 0.05% by weight to about 50% by weight of the tooth whitening agent, based on the total weight of the tooth whitening agent and the polymer.
2. The dental whitening composition of claim 1 wherein the polymer further comprises a repeating unit comprising a modulating group.
3. The dental whitening composition of claim 1 wherein the tooth whitening agent is selected from the group consisting of a hypochlorite, an organic peroxide, an inorganic peroxide, a hydroperoxide, hydrogen peroxide, a peracid, carbamide peroxide, and combinations thereof.

CLAIMS APPENDIX

Serial No. 10/626,142

Docket No. 58359US003

Page CA2 of CA22

5. The dental whitening composition of claim 1 wherein the repeating unit comprising the polar or polarizable group is selected from the group consisting of acrylic acid, itaconic acid, N-isopropylacrylamide, and combinations thereof.
6. The dental whitening composition of claim 1 wherein the repeating unit comprising the fluoride releasing group comprises tetrafluoroborate anions.
7. The dental whitening composition of claim 1 wherein the repeating unit comprising the fluoride releasing group is trimethylammoniummethyl methacrylate tetrafluoroborate.
8. A dental whitening composition suitable for coating oral surfaces comprising:
 - greater than 10% by weight of a tooth whitening agent, based on the total weight of the dental whitening composition; and
 - a polymer comprising:
 - a repeating unit comprising a polar or polarizable group; and
 - a repeating unit comprising a fluoride releasing group,

CLAIMS APPENDIX

Serial No. 10/626,142

Docket No. 58359US003

Page CA3 of CA22

wherein the repeating unit comprising the polar or polarizable group is different than the repeating unit comprising the fluoride releasing group.

9. The dental whitening composition of claim 8 wherein the polymer further comprises a repeating unit comprising a modulating group.

10. The dental whitening composition of claim 8 wherein the tooth whitening agent is selected from the group consisting of a hypochlorite, a organic peroxide, an inorganic peroxide, a hydroperoxide, hydrogen peroxide, a peracid, carbamide peroxide, and combinations thereof.

11. The dental whitening composition of claim 8 wherein the repeating unit comprising the polar or polarizable group is selected from the group consisting of acrylic acid, itaconic acid, N-isopropylacrylamide, and combinations thereof.

12. The dental whitening composition of claim 8 wherein the repeating unit comprising the fluoride releasing group comprises tetrafluoroborate anions.

CLAIMS APPENDIX

Serial No. 10/626,142

Docket No. 58359US003

Page CA4 of CA22

13. The dental whitening composition of claim 8 wherein the repeating unit comprising the fluoride releasing group is trimethylammoniummethyl methacrylate tetrafluoroborate.

14. The dental whitening composition of claim 8 wherein the polymer further comprises a reactive group.

15. A dental whitening composition suitable for coating oral surfaces comprising:

a tooth whitening agent; and

a polymer comprising:

a repeating unit comprising a polar or polarizable group; and

a repeating unit comprising a fluoride releasing group,

with the proviso that the dental whitening composition does not include hydrogen peroxide,

wherein the repeating unit comprising the polar or polarizable group is different than the repeating unit comprising the fluoride releasing group, and

wherein the composition comprises about 0.05% by weight to about 50% by weight of the tooth whitening agent, based on the total weight of the tooth whitening agent and the polymer.

CLAIMS APPENDIX

Serial No. 10/626,142

Docket No. 58359US003

Page CA5 of CA22

16. The dental whitening composition of claim 15 wherein the polymer further comprises a repeating unit comprising a modulating group.

17. The dental whitening composition of claim 15 wherein the tooth whitening agent is selected from the group consisting of a hypochlorite, an organic peroxide, an inorganic peroxide, a hydroperoxide, a peracid, carbamide peroxide, and combinations thereof.

19. The dental whitening composition of claim 15 wherein the repeating unit comprising the polar or polarizable group is selected from the group consisting of acrylic acid, itaconic acid, N-isopropylacrylamide, and combinations thereof.

20. The dental whitening composition of claim 15 wherein the repeating unit comprising the fluoride releasing group comprises tetrafluoroborate anions.

21. The dental whitening composition of claim 15 wherein the repeating unit comprising the fluoride releasing group is trimethylammoniummethyl methacrylate tetrafluoroborate.

CLAIMS APPENDIX

Serial No. 10/626,142

Docket No. 58359US003

Page CA6 of CA22

22. The dental whitening composition of claim 15 wherein the polymer further comprises a reactive group.

23. A dental whitening composition suitable for coating oral surfaces comprising:

a tooth whitening agent; and

a polymer comprising:

a repeating unit comprising a polar or polarizable group; and

a repeating unit comprising a fluoride releasing group comprising tetrafluoroborate anions,

wherein the repeating unit comprising the polar or polarizable group is different than the repeating unit comprising the fluoride releasing group, and

wherein the composition comprises about 0.05% by weight to about 50% by weight of the tooth whitening agent, based on the total weight of the tooth whitening agent and the polymer.

24. The dental whitening composition of claim 23 wherein the polymer further comprises a repeating unit comprising a modulating group.

CLAIMS APPENDIX

Serial No. 10/626,142

Docket No. 58359US003

Page CA7 of CA22

25. The dental whitening composition of claim 23 wherein the tooth whitening agent is selected from the group consisting of a hypochlorite, an organic peroxide, an inorganic peroxide, a hydroperoxide, hydrogen peroxide, a peracid, carbamide peroxide, and combinations thereof.
27. The dental whitening composition of claim 23 wherein the repeating unit comprising the polar or polarizable group is selected from the group consisting of acrylic acid, itaconic acid, N-isopropylacrylamide, and combinations thereof.
28. The dental whitening composition of claim 23 wherein the repeating unit comprising the fluoride releasing group is trimethylammoniummethyl methacrylate tetrafluoroborate.
29. The dental whitening composition of claim 23 wherein the polymer further comprises a reactive group.
30. A dental whitening composition suitable for coating oral surfaces comprising:
 - a tooth whitening agent; and
 - a polymer comprising:
 - a repeating unit comprising a polar or polarizable group;

CLAIMS APPENDIX

Serial No. 10/626,142

Docket No. 58359US003

Page CA8 of CA22

a repeating unit comprising a fluoride releasing group; and
a repeating unit comprising a group selected from the group consisting of a hydrophobic hydrocarbon group, a graft polysiloxane chain, a hydrophobic fluorine-containing group, and combinations thereof,

with the proviso that the polymer does not include pendant ethylenically unsaturated moieties,

wherein the repeating unit comprising the polar or polarizable group is different than the repeating unit comprising the fluoride releasing group, and

wherein the composition comprises about 0.05% by weight to about 50% by weight of the tooth whitening agent, based on the total weight of the tooth whitening agent and the polymer.

31. The dental whitening composition of claim 30 wherein the polymer further comprises a repeating unit comprising a modulating group.

32. The dental whitening composition of claim 30 wherein the tooth whitening agent is selected from the group consisting of a hypochlorite, an organic peroxide, an inorganic peroxide, a hydroperoxide, hydrogen peroxide, a peracid, carbamide peroxide, and combinations thereof.

CLAIMS APPENDIX

Serial No. 10/626,142

Docket No. 58359US003

Page CA9 of CA22

34. The dental whitening composition of claim 30 wherein the repeating unit comprising the polar or polarizable group is selected from the group consisting of acrylic acid, itaconic acid, N-isopropylacrylamide, and combinations thereof.
35. The dental whitening composition of claim 30 wherein the repeating unit comprising the hydrophobic hydrocarbon group is octadecylacrylate.
36. The dental whitening composition of claim 30 wherein the repeating unit comprising the hydrophobic fluorine-containing group is selected from the group consisting of 2-(methyl(nonafluorobutyl)sulfonyl)amino)ethyl acrylate, 2-(methyl(nonafluorobutyl)sulfonyl)amino)ethyl methacrylate, and combinations thereof.
37. A dental whitening composition suitable for coating oral surfaces comprising:
 - greater than 10% by weight of a tooth whitening agent, based on the total weight of the dental whitening composition; and
 - a polymer comprising:
 - a repeating unit comprising a polar or polarizable group;

CLAIMS APPENDIX

Serial No. 10/626,142

Docket No. 58359US003

Page CA10 of CA22

a repeating unit comprising a fluoride releasing group; and
a repeating unit comprising a group selected from the group consisting of a hydrophobic hydrocarbon group, a graft polysiloxane chain, a hydrophobic fluorine-containing group, and combinations thereof,

wherein the repeating unit comprising the polar or polarizable group is different than the repeating unit comprising the fluoride releasing group.

38. The dental whitening composition of claim 37 wherein the polymer further comprises a repeating unit comprising a modulating group.

39. The dental whitening composition of claim 37 wherein the tooth whitening agent is selected from the group consisting of a hypochlorite, an organic peroxide, an inorganic peroxide, a hydroperoxide, hydrogen peroxide, a peracid, carbamide peroxide, and combinations thereof.

40. The dental whitening composition of claim 37 wherein the polymer further comprises a reactive group.

41. A dental whitening composition suitable for coating oral surfaces comprising:

CLAIMS APPENDIX

Serial No. 10/626,142

Docket No. 58359US003

Page CA11 of CA22

a tooth whitening agent; and

a polymer comprising:

a repeating unit comprising a polar or polarizable group;

a repeating unit comprising a fluoride releasing group; and

a repeating unit comprising a group selected from the group consisting of a hydrophobic hydrocarbon group, a graft polysiloxane chain, a hydrophobic fluorine-containing group, and combinations thereof,

wherein the repeating unit comprising the polar or polarizable group is different than the repeating unit comprising the fluoride releasing group, and

with the proviso that the dental whitening composition does not include hydrogen peroxide, and

wherein the composition comprises about 0.05% by weight to about 50% by weight of the tooth whitening agent, based on the total weight of the tooth whitening agent and the polymer.

42. The dental whitening composition of claim 41 wherein the polymer further comprises a repeating unit comprising a modulating group.

CLAIMS APPENDIX

Serial No. 10/626,142

Docket No. 58359US003

Page CA12 of CA22

43. The dental whitening composition of claim 41 wherein the tooth whitening agent is selected from the group consisting of a hypochlorite, an organic peroxide, an inorganic peroxide, a hydroperoxide, a peracid, carbamide peroxide, and combinations thereof.

45. The dental whitening composition of claim 41 wherein the polymer further comprises a reactive group.

46. A coating on hard tissue surfaces or surfaces of the oral environment comprising:

a tooth whitening agent; and

a polymer comprising:

a repeating unit comprising a polar or polarizable group; and

a repeating unit comprising a fluoride releasing group,

with the proviso that the polymer does not include pendant ethylenically unsaturated moieties,

wherein the repeating unit comprising the polar or polarizable group is different than the repeating unit comprising the fluoride releasing group, and

wherein the coating comprises about 0.05% by weight to about 50% by weight of the tooth whitening agent, based on the total weight of the tooth whitening agent and the polymer.

CLAIMS APPENDIX

Serial No. 10/626,142

Docket No. 58359US003

Page CA13 of CA22

47. A coating on hard tissue surfaces or surfaces of the oral environment comprising:
- greater than 10% by weight of a tooth whitening agent, based on the total weight of the coating; and
- a polymer comprising:
- a repeating unit comprising a polar or polarizable group; and
- a repeating unit comprising a fluoride releasing group,
wherein the repeating unit comprising the polar or polarizable group is different than the repeating unit comprising the fluoride releasing group.,

48. A coating on hard tissue surfaces or surfaces of the oral environment comprising:
- a tooth whitening agent; and
- a polymer comprising:
- a repeating unit comprising a polar or polarizable group; and
- a repeating unit comprising a fluoride releasing group,
wherein the repeating unit comprising the polar or polarizable group is different than the repeating unit comprising the fluoride releasing group, and

CLAIMS APPENDIX

Serial No. 10/626,142

Docket No. 58359US003

Page CA14 of CA22

with the proviso that the dental whitening composition does not include hydrogen peroxide, and

wherein the coating comprises about 0.05% by weight to about 50% by weight of the tooth whitening agent, based on the total weight of the tooth whitening agent and the polymer.

49. A coating on hard tissue surfaces or surfaces of the oral environment comprising:

a tooth whitening agent; and

a polymer comprising:

a repeating unit comprising a polar or polarizable group; and

a repeating unit comprising a fluoride releasing group comprising tetrafluoroborate anions,

wherein the repeating unit comprising the polar or polarizable group is different than the repeating unit comprising the fluoride releasing group, and

wherein the coating comprises about 0.05% by weight to about 50% by weight of the tooth whitening agent, based on the total weight of the tooth whitening agent and the polymer.

50. A coating on hard tissue surfaces or surfaces of the oral environment comprising:

a tooth whitening agent; and

CLAIMS APPENDIX

Serial No. 10/626,142

Docket No. 58359US003

Page CA15 of CA22

a polymer comprising:

a repeating unit comprising a polar or polarizable group;

a repeating unit comprising a fluoride releasing group; and

a repeating unit comprising a group selected from the group consisting of a hydrophobic hydrocarbon group, a graft polysiloxane chain, a hydrophobic fluorine-containing group, and combinations thereof,

with the proviso that the polymer does not include pendant ethylenically unsaturated moieties,

wherein the repeating unit comprising the polar or polarizable group is different than the repeating unit comprising the fluoride releasing group, and

wherein the coating comprises about 0.05% by weight to about 50% by weight of the tooth whitening agent, based on the total weight of the tooth whitening agent and the polymer.

51. A coating on hard tissue surfaces or surfaces of the oral environment comprising:

greater than 10% by weight of a tooth whitening agent, based on the total weight of the coating; and

a polymer comprising:

a repeating unit comprising a polar or polarizable group;

CLAIMS APPENDIX

Serial No. 10/626,142

Docket No. 58359US003

Page CA16 of CA22

a repeating unit comprising a fluoride releasing group; and
a repeating unit comprising a group selected from the group consisting of a hydrophobic hydrocarbon group, a graft polysiloxane chain, a hydrophobic fluorine-containing group, and combinations thereof,
wherein the repeating unit comprising the polar or polarizable group is different than the repeating unit comprising the fluoride releasing group.

52. A coating on hard tissue surfaces or surfaces of the oral environment comprising:
a tooth whitening agent; and
a polymer comprising:
a repeating unit comprising a polar or polarizable group;
a repeating unit comprising a fluoride releasing group; and
a repeating unit comprising a group selected from the group consisting of a hydrophobic hydrocarbon group, a graft polysiloxane chain, a hydrophobic fluorine-containing group, and combinations thereof,
wherein the repeating unit comprising the polar or polarizable group is different than the repeating unit comprising the fluoride releasing group, and

CLAIMS APPENDIX

Serial No. 10/626,142

Docket No. 58359US003

Page CA17 of CA22

with the proviso that the dental whitening composition does not include hydrogen peroxide, and

wherein the coating comprises about 0.05% by weight to about 50% by weight of the tooth whitening agent, based on the total weight of the tooth whitening agent and the polymer.

53. A method of whitening teeth comprising applying a dental whitening composition according to claim 1 to a hard tissue surface or a surface of the oral environment.

54. The method of claim 53 wherein applying the composition is selected from the group consisting of painting the composition, brushing the composition, syringing the composition, misting the composition, spraying the composition, applying a substrate having the composition thereon, and combinations thereof.

55. The method of claim 53 wherein the composition is in a form selected from the group consisting of a dispersion, a suspension, an emulsion, a solution, and combinations thereof.

56. The method of claim 53 wherein the composition is an aqueous composition.

CLAIMS APPENDIX

Serial No. 10/626,142

Docket No. 58359US003

Page CA18 of CA22

57. A method of whitening teeth comprising applying a dental whitening composition according to claim 8 to a hard tissue surface or a surface of the oral environment.
58. The method of claim 57 wherein applying the composition is selected from the group consisting of painting the composition, brushing the composition, syringing the composition, misting the composition, spraying the composition, applying a substrate having the composition thereon, and combinations thereof.
59. The method of claim 57 wherein the composition is in a form selected from the group consisting of a dispersion, a suspension, an emulsion, a solution, and combinations thereof.
60. The method of claim 57 wherein the composition is an aqueous composition.
61. A method of whitening teeth comprising applying a dental whitening composition according to claim 15 to a hard tissue surface or a surface of the oral environment.
62. The method of claim 61 wherein applying the composition is selected from the group consisting of painting the composition, brushing the composition, syringing the composition,

CLAIMS APPENDIX

Serial No. 10/626,142

Docket No. 58359US003

Page CA19 of CA22

misting the composition, spraying the composition, applying a substrate having the composition thereon, and combinations thereof.

63. The method of claim 61 wherein the composition is in a form selected from the group consisting of a dispersion, a suspension, an emulsion, a solution, and combinations thereof.

64. The method of claim 61 wherein the composition is an aqueous composition.

65. A method of whitening teeth comprising applying a dental whitening composition according to claim 23 to a hard tissue surface or a surface of the oral environment.

66. The method of claim 65 wherein applying the composition is selected from the group consisting of painting the composition, brushing the composition, syringing the composition, misting the composition, spraying the composition, applying a substrate having the composition thereon, and combinations thereof.

67. The method of claim 65 wherein the composition is in a form selected from the group consisting of a dispersion, a suspension, an emulsion, a solution, and combinations thereof.

CLAIMS APPENDIX

Serial No. 10/626,142

Docket No. 58359US003

Page CA20 of CA22

68. The method of claim 65 wherein the composition is an aqueous composition.

69. A method of whitening teeth comprising applying a dental whitening composition according to claim 30 to a hard tissue surface or a surface of the oral environment.

70. The method of claim 69 wherein applying the composition is selected from the group consisting of painting the composition, brushing the composition, syringing the composition, misting the composition, spraying the composition, applying a substrate having the composition thereon, and combinations thereof.

71. The method of claim 69 wherein the composition is in a form selected from the group consisting of a dispersion, a suspension, an emulsion, a solution, and combinations thereof.

72. The method of claim 69 wherein the composition is an aqueous composition.

73. A method of whitening teeth comprising applying a dental whitening composition according to claim 37 to a hard tissue surface or a surface of the oral environment.

CLAIMS APPENDIX

Serial No. 10/626,142

Docket No. 58359US003

Page CA21 of CA22

74. The method of claim 73 wherein applying the composition is selected from the group consisting of painting the composition, brushing the composition, syringing the composition, misting the composition, spraying the composition, applying a substrate having the composition thereon, and combinations thereof.

75. The method of claim 73 wherein the composition is in a form selected from the group consisting of a dispersion, a suspension, an emulsion, a solution, and combinations thereof.

76. The method of claim 73 wherein the composition is an aqueous composition.

77. A method of whitening teeth comprising applying a dental whitening composition according to claim 41 to a hard tissue surface or a surface of the oral environment.

78. The method of claim 77 wherein applying the composition is selected from the group consisting of painting the composition, brushing the composition, syringing the composition, misting the composition, spraying the composition, applying a substrate having the composition thereon, and combinations thereof.

CLAIMS APPENDIX

Serial No. 10/626,142

Docket No. 58359US003

Page CA22 of CA22

79. The method of claim 77 wherein the composition is in a form selected from the group consisting of a dispersion, a suspension, an emulsion, a solution, and combinations thereof.

80. The method of claim 77 wherein the composition is an aqueous composition.



EVIDENCE APPENDIX

Serial No. 10/626,142

Docket No. 58359US003

1. Aasen et al. (U.S. Patent No. 4,871,786) (entered into the record by citation within the Form 1449 accompanying the Information Disclosure Statement mailed 26 July 2004).
2. Rozzi et al. (U.S. Patent No. 5,607,663) (entered into the record by citation within the Form 1449 accompanying the Information Disclosure Statement mailed 26 July 2004).
3. Mitra et al. (U.S. Patent No. 5,888,491) (entered into the record by citation within the Form 1449 accompanying the Information Disclosure Statement mailed 26 July 2004).
4. Majeti et al. (U.S. Patent No. 7,025,950) (entered into the record by citation within a Form 892 and the accompanying the non-final Office Action mailed 9 October 2007).



RELATED PROCEEDINGS APPENDIX

Serial No. 10/626,142

Docket No. 58359US003

None.



CITED AUTHORITIES AND DOCUMENTS

Serial No. 10/626,142

Docket No. 58359US003

1. M.P.E.P. § 2141.02(VI), 8th Ed., Rev. 6, Sept. 2007, pages 2100-123 to 2100-126.
2. M.P.E.P. § 2142, 8th Ed., Rev. 6, Sept. 2007, pages 2100-127 to 2100-128.



PATENTABILITY

2141.02

766 (Fed. Cir. 1985) (Claims at issue were directed to an instrument marker pen body, the improvement comprising a pen arm holding means having an integrally molded hinged member for folding over against the pen body. Although the patent owners argued the hinge and fastener art was nonanalogous, the court held that the problem confronting the inventor was the need for a simple holding means to enable frequent, secure attachment and easy removal of a marker pen to and from a pen arm, and one skilled in the pen art trying to solve that problem would have looked to the fastener and hinge art.); and *Ex parte Goodyear Tire & Rubber Co.*, 230 USPQ 357 (Bd. Pat. App. & Inter. 1985) (A reference in the clutch art was held reasonably pertinent to the friction problem faced by applicant, whose claims were directed to a braking material, because brakes and clutches utilize interfacing materials to accomplish their respective purposes.).

V. ANALOGY IN THE ELECTRICAL ARTS

See, for example, *** Medtronic, Inc. v. Cardiac Pacemakers*, 721 F.2d 1563, 220 USPQ 97 (Fed. Cir. 1983) (Patent claims were drawn to a cardiac pacemaker which comprised, among other components, a runaway inhibitor means for preventing a pacemaker malfunction from causing pulses to be applied at too high a frequency rate. Two references disclosed circuits used in high power, high frequency devices which inhibited the runaway of pulses from a pulse source. The court held that one of ordinary skill in the pacemaker designer art faced with a rate-limiting problem would look to the solutions of others faced with rate limiting problems, and therefore the references were in an analogous art.).

VI. EXAMPLES OF ANALOGY IN THE DESIGN ARTS

See MPEP § 1504.03 for a discussion of the relevant case law setting forth the general requirements for analogous art in design applications.

For examples of analogy in the design arts, see *In re Rosen*, 673 F.2d 388, 213 USPQ 347 (CCPA 1982) (The design at issue was a coffee table of contemporary styling. The court held designs of contemporary furniture other than coffee tables, such as the desk and circular glass table top designs of the references relied upon, would reasonably fall within the scope of the

knowledge of the designer of ordinary skill.); *Ex parte Pappas*, 23 USPQ2d 1636 (Bd. Pat. App. & Inter. 1992) (At issue was an ornamental design for a feed bunk with an inclined corner configuration. Examiner relied upon references to a bunk lacking the inclined corners claimed by appellant and the *Architectural Precast Concrete Drafting Handbook*. The Board found the *Architectural Precast Concrete Drafting Handbook* was analogous art, noting that a bunk may be a wood or concrete trough, and that both references relied upon "disclose structures in which at least one upstanding leg is generally perpendicular to a base portion to define a corner configuration between the leg and base portion."); *In re Butera*, 1 F.3d 1252, 28 USPQ2d 1399 (Fed. Cir. 1993) (unpublished - not citable as precedent) (The claimed invention, a spherical design for a combined insect repellent and air freshener, was rejected by the Board as obvious over a single reference to a design for a metal ball anode. The court reversed, holding the reference design to be nonanalogous art. "A prior design is of the type claimed if it has the same general use as that claimed in the design patent application One designing a combined insect repellent and air freshener would therefore not have reason to know of or look to a design for a metal ball anode." 28 USPQ2d at 1400.).

2141.02 Differences Between Prior Art and Claimed Invention [R-5]

Ascertaining the differences between the prior art and the claims at issue requires interpreting the claim language, and considering both the invention and the prior art references as a whole. See MPEP § 2111 - § 2116.01 for case law pertaining to claim interpretation.

I. THE CLAIMED INVENTION AS A WHOLE MUST BE CONSIDERED

In determining the differences between the prior art and the claims, the question under 35 U.S.C. 103 is not whether the differences themselves would have been obvious, but whether the claimed invention as a whole would have been obvious. *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 218 USPQ 871 (Fed. Cir. 1983); *Schenck v. Nortron Corp.*, 713 F.2d 782, 218 USPQ 698 (Fed. Cir. 1983) (Claims were directed to a vibratory testing machine (a hard-bearing wheel

balancer) comprising a holding structure, a base structure, and a supporting means which form “a single integral and gaplessly continuous piece.” *Nortron* argued the invention is just making integral what had been made in four bolted pieces, improperly limiting the focus to a structural difference from the prior art and failing to consider the invention as a whole. The prior art perceived a need for mechanisms to dampen resonance, whereas the inventor eliminated the need for dampening via the one-piece gapless support structure. “Because that insight was contrary to the understandings and expectations of the art, the structure effectuating it would not have been obvious to those skilled in the art.” 713 F.2d at 785, 218 USPQ at 700 (citations omitted).).

See also *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) (Claims were directed to a three step process for preparing sweetened foods and drinks. The first two steps were directed to a process of producing high purity maltose (the sweetener), and the third was directed to adding the maltose to foods and drinks. The parties agreed that the first two steps were unobvious but formed a known product and the third step was obvious. The Solicitor argued the preamble was directed to a process for preparing foods and drinks sweetened mildly and thus the specific method of making the high purity maltose (the first two steps in the claimed process) should not be given weight, analogizing with product-by-process claims. The court held “due to the admitted unobviousness of the first two steps of the claimed combination of steps, the subject matter as a whole would not have been obvious to one of ordinary skill in the art at the time the invention was made.” 535 F.2d at 69, 190 USPQ at 17 (emphasis in original). The preamble only recited the purpose of the process and did not limit the body of the claim. Therefore, the claimed process was a three step process, not the product formed by two steps of the process or the third step of using that product.).

II. DISTILLING THE INVENTION DOWN TO A “GIST” OR “THRUST” OF AN INVENTION DISREGARDS “AS A WHOLE” REQUIREMENT

Distilling an invention down to the “gist” or “thrust” of an invention disregards the requirement of analyzing the subject matter “as a whole.” *W.L. Gore*

& Associates, Inc. v. *Garlock, Inc.*, 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983), cert. denied, 469 U.S. 851 (1984) (restricting consideration of the claims to a 10% per second rate of stretching of unsintered PTFE and disregarding other limitations resulted in treating claims as though they read differently than allowed); *Bausch & Lomb v. Barnes-Hind/Hydrocurve, Inc.*, 796 F.2d 443, 447-49, 230 USPQ 416, 419-20 (Fed. Cir. 1986), cert. denied, 484 U.S. 823 (1987) (District court focused on the “concept of forming ridgeless depressions having smooth rounded edges using a laser beam to vaporize the material,” but “disregarded express limitations that the product be an ophthalmic lens formed of a transparent cross-linked polymer and that the laser marks be surrounded by a smooth surface of unsublimated polymer.”). See also *Jones v. Hardy*, 727 F.2d 1524, 1530, 220 USPQ 1021, 1026 (Fed. Cir. 1984) (“treating the advantage as the invention disregards statutory requirement that the invention be viewed ‘as a whole’”); *Panduit Corp. v. Dennison Mfg. Co.*, 810 F.2d 1561, 1 USPQ2d 1593 (Fed. Cir.), cert. denied, 481 U.S. 1052 (1987) (district court improperly distilled claims down to a one word solution to a problem).

III. DISCOVERING SOURCE/CAUSE OF A PROBLEM IS PART OF “AS A WHOLE” INQUIRY

“[A] patentable invention may lie in the discovery of the source of a problem even though the remedy may be obvious once the source of the problem is identified. This is part of the ‘subject matter as a whole’ which should always be considered in determining the obviousness of an invention under 35 U.S.C. § 103.” *In re Sponnoble*, 405 F.2d 578, 585, 160 USPQ 237, 243 (CCPA 1969). However, “discovery of the cause of a problem . . . does not always result in a patentable invention. . . . [A] different situation exists where the solution is obvious from prior art which contains the same solution for a similar problem.” *In re Wiseman*, 596 F.2d 1019, 1022, 201 USPQ 658, 661 (CCPA 1979) (emphasis in original).

In *In re Sponnoble*, the claim was directed to a plural compartment mixing vial wherein a center seal plug was placed between two compartments for temporarily isolating a liquid-containing compartment from a solids-containing compartment. The claim differed from the prior art in the selection of butyl rubber

with a silicone coating as the plug material instead of natural rubber. The prior art recognized that leakage from the liquid to the solids compartment was a problem, and considered the problem to be a result of moisture passing around the center plug because of microscopic fissures inherently present in molded or blown glass. The court found the inventor discovered the cause of moisture transmission was through the center plug, and there was no teaching in the prior art which would suggest the necessity of selecting applicant's plug material which was more impervious to liquids than the natural rubber plug of the prior art.

In *In re Wiseman*, 596 F.2d at 1022, 201 USPQ at 661, claims directed to grooved carbon disc brakes wherein the grooves were provided to vent steam or vapor during a braking action to minimize fading of the brakes were rejected as obvious over a reference showing carbon disc brakes without grooves in combination with a reference showing grooves in noncarbon disc brakes for the purpose of cooling the faces of the braking members and eliminating dust, thereby reducing fading of the brakes. The court affirmed the rejection, holding that even if applicants discovered the cause of a problem, the solution would have been obvious from the prior art which contained the same solution (inserting grooves in disc brakes) for a similar problem.

IV. APPLICANTS ALLEGING DISCOVERY OF A SOURCE OF A PROBLEM MUST PROVIDE SUBSTANTIATING EVIDENCE

Applicants who allege they discovered the source of a problem must provide evidence substantiating the allegation, either by way of affidavits or declarations, or by way of a clear and persuasive assertion in the specification. *In re Wiseman*, 596 F.2d 1019, 201 USPQ 658 (CCPA 1979) (unsubstantiated statement of counsel was insufficient to show appellants discovered source of the problem); *In re Kaslow*, 707 F.2d 1366, 217 USPQ 1089 (Fed. Cir. 1983) (Claims were directed to a method for redeeming merchandising coupons which contain a UPC "5-by-5" bar code wherein, among other steps, the memory at each supermarket would identify coupons by manufacturer and transmit the data to a central computer to provide

an audit thereby eliminating the need for clearinghouses and preventing retailer fraud. In challenging the propriety of an obviousness rejection, appellant argued he discovered the source of a problem (retailer fraud and manual clearinghouse operations) and its solution. The court found appellant's specification did not support the argument that he discovered the source of the problem with respect to retailer fraud, and that the claimed invention failed to solve the problem of manual clearinghouse operations.).

V. DISCLOSED INHERENT PROPERTIES ARE PART OF "AS A WHOLE" INQUIRY

"In determining whether the invention as a whole would have been obvious under 35 U.S.C. 103, we must first delineate the invention as a whole. In delineating the invention as a whole, we look not only to the subject matter which is literally recited in the claim in question... but also to those properties of the subject matter which are inherent in the subject matter *and* are disclosed in the specification. . . Just as we look to a chemical and its properties when we examine the obviousness of a composition of matter claim, it is this invention *as a whole*, and not some part of it, which must be obvious under 35 U.S.C. 103." *In re Antonie*, 559 F.2d 618, 620, 195 USPQ 6,8 (CCPA 1977) (emphasis in original) (citations omitted) (The claimed wastewater treatment device had a tank volume to contractor area of 0.12 gal./sq. ft. The court found the invention as a whole was the ratio of 0.12 and its inherent property that the claimed devices maximized treatment capacity regardless of other variables in the devices. The prior art did not recognize that treatment capacity was a function of the tank volume to contractor ratio, and therefore the parameter optimized was not recognized in the art to be a result-effective variable.). See also *In re Papesch*, 315 F.2d 381, 391, 137 USPQ 43, 51 (CCPA 1963) ("From the standpoint of patent law, a compound and all its properties are inseparable.").

Obviousness cannot be predicated on what is not known at the time an invention is made, even if the inherency of a certain feature is later established. *In re Rijckaert*, 9 F.2d 1531, 28 USPQ2d 1955 (Fed. Cir. 1993). See MPEP § 2112 for the requirements of rejections based on inherency.

VI. PRIOR ART MUST BE CONSIDERED IN ITS ENTIRETY, INCLUDING DISCLOSURES THAT TEACH AWAY FROM THE CLAIMS

A prior art reference must be considered in its entirety, i.e., as a whole, including portions that would lead away from the claimed invention. *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983), *cert. denied*, 469 U.S. 851 (1984) (Claims were directed to a process of producing a porous article by expanding shaped, unsintered, highly crystalline poly(tetrafluoroethylene) (PTFE) by stretching said PTFE at a 10% per second rate to more than five times the original length. The prior art teachings with regard to unsintered PTFE indicated the material does not respond to conventional plastics processing, and the material should be stretched slowly. A reference teaching rapid stretching of conventional plastic polypropylene with reduced crystallinity combined with a reference teaching stretching unsintered PTFE would not suggest rapid stretching of highly crystalline PTFE, in light of the disclosures in the art that teach away from the invention, i.e., that the conventional polypropylene should have reduced crystallinity before stretching, and that PTFE should be stretched slowly.).

However, “the prior art’s mere disclosure of more than one alternative does not constitute a teaching away from any of these alternatives because such disclosure does not criticize, discredit, or otherwise discourage the solution claimed....” *In re Fulton*, 391 F.3d 1195, 1201, 73 USPQ2d 1141, 1146 (Fed. Cir. 2004). >See also MPEP § 2123.<

2141.03 Level of Ordinary Skill in the Art [R-6]

>

I. < FACTORS TO CONSIDER IN DETERMINING LEVEL OF ORDINARY SKILL

**>The person of ordinary skill in the art is a hypothetical person who is presumed to have known the relevant art at the time of the invention. Factors that may be considered in determining the level of ordinary skill in the art may include: (A) “type of problems encountered in the art;” (B) “prior art solutions to those problems;” (C) “rapidity with which innova-

tions are made;” (D) “sophistication of the technology; and” (E) “educational level of active workers in the field. In a given case, every factor may not be present, and one or more factors may predominate.” *In re GPAC*, 57 F.3d 1573, 1579, 35 USPQ2d 1116, 1121 (Fed. Cir. 1995); *Custom Accessories, Inc. v. Jeffrey-Allan Industries, Inc.*, 807 F.2d 955, 962, 1 USPQ2d 1196, 1201 (Fed. Cir. 1986); *Environmental Designs, Ltd. V. Union Oil Co.*, 713 F.2d 693, 696, 218 USPQ 865, 868 (Fed. Cir. 1983).

“A person of ordinary skill in the art is also a person of ordinary creativity, not an automaton.” *KSR International Co. v. Teleflex Inc.*, 550 U.S. ___, ___, 82 USPQ2d 1385, 1397 (2007). “[I]n many cases a person of ordinary skill will be able to fit the teachings of multiple patents together like pieces of a puzzle.” *Id.* Office personnel may also take into account “the inferences and creative steps that a person of ordinary skill in the art would employ.” *Id.* at ___, 82 USPQ2d at 1396. <

The “hypothetical ‘person having ordinary skill in the art’ to which the claimed subject matter pertains would, of necessity have the capability of understanding the scientific and engineering principles applicable to the pertinent art.” *Ex parte Hiyamizu*, 10 USPQ2d 1393, 1394 (Bd. Pat. App. & Inter. 1988) (The Board disagreed with the examiner’s definition of one of ordinary skill in the art (a doctorate level engineer or scientist working at least 40 hours per week in semiconductor research or development), finding that the hypothetical person is not definable by way of credentials, and that the evidence in the application did not support the conclusion that such a person would require a doctorate or equivalent knowledge in science or engineering.).

References which do not qualify as prior art because they postdate the claimed invention may be relied upon to show the level of ordinary skill in the art at or around the time the invention was made. *Ex parte Erlich*, 22 USPQ 1463 (Bd. Pat. App. & Inter. 1992). Moreover, documents not available as prior art because the documents were not widely disseminated may be used to demonstrate the level of ordinary skill in the art. For example, the document may be relevant to establishing “a motivation to combine which is implicit in the knowledge of one of ordinary skill in the art.” *National Steel Car Ltd. v. Canadian Pacific Railway Ltd.*, 357 F.3d 1319, 1338, 69 USPQ2d 1641,



1656 (Fed. Cir. 2004)(holding that a drawing made by an engineer that was not prior art may nonetheless “be used to demonstrate a motivation to combine implicit in the knowledge of one of ordinary skill in the art”).

>

II. < SPECIFYING A PARTICULAR LEVEL OF SKILL IS NOT NECESSARY WHERE THE PRIOR ART ITSELF REFLECTS AN APPROPRIATE LEVEL

If the only facts of record pertaining to the level of skill in the art are found within the prior art of record, the court has held that an invention may be held to have been obvious without a specific finding of a particular level of skill where the prior art itself reflects an appropriate level. *Chore-Time Equipment, Inc. v. Cumberland Corp.*, 713 F.2d 774, 218 USPQ 673 (Fed. Cir. 1983). See also *Okajima v. Bourdeau*, 261 F.3d 1350, 1355, 59 USPQ2d 1795, 1797 (Fed. Cir. 2001).

>

III. < ASCERTAINING LEVEL OF ORDINARY SKILL IS NECESSARY TO MAINTAIN OBJECTIVITY

“The importance of resolving the level of ordinary skill in the art lies in the necessity of maintaining objectivity in the obviousness inquiry.” *Ryko Mfg. Co. v. Nu-Star, Inc.*, 950 F.2d 714, 718, 21 USPQ2d 1053, 1057 (Fed. Cir. 1991). The examiner must ascertain what would have been obvious to one of ordinary skill in the art at the time the invention was made, and not to the inventor, a judge, a layman, those skilled in remote arts, or to geniuses in the art at hand. *Environmental Designs, Ltd. v. Union Oil Co.*, 713 F.2d 693, 218 USPQ 865 (Fed. Cir. 1983), cert. denied, 464 U.S. 1043 (1984).

2142 Legal Concept of *Prima Facie* Obviousness [R-6]

The legal concept of *prima facie* obviousness is a procedural tool of examination which applies broadly to all arts. It allocates who has the burden of going forward with production of evidence in each step of the examination process. See *In re Rinehart*, 531 F.2d 1048, 189 USPQ 143 (CCPA 1976); *In re Linter*, 458 F.2d 1013, 173 USPQ 560 (CCPA 1972); *In re Saun-*

ders, 444 F.2d 599, 170 USPQ 213 (CCPA 1971); *In re Tiffin*, 443 F.2d 394, 170 USPQ 88 (CCPA 1971), amended, 448 F.2d 791, 171 USPQ 294 (CCPA 1971); *In re Warner*, 379 F.2d 1011, 154 USPQ 173 (CCPA 1967), cert. denied, 389 U.S. 1057 (1968). The examiner bears the initial burden of factually supporting any *prima facie* conclusion of obviousness. If the examiner does not produce a *prima facie* case, the applicant is under no obligation to submit evidence of nonobviousness. If, however, the examiner does produce a *prima facie* case, the burden of coming forward with evidence or arguments shifts to the applicant who may submit additional evidence of nonobviousness, such as comparative test data showing that the claimed invention possesses improved properties not expected by the prior art. The initial evaluation of *prima facie* obviousness thus relieves both the examiner and applicant from evaluating evidence beyond the prior art and the evidence in the specification as filed until the art has been shown to *>render obvious< the claimed invention.

To reach a proper determination under 35 U.S.C. 103, the examiner must step backward in time and into the shoes worn by the hypothetical “person of ordinary skill in the art” when the invention was unknown and just before it was made. In view of all factual information, the examiner must then make a determination whether the claimed invention “as a whole” would have been obvious at that time to that person. Knowledge of applicant’s disclosure must be put aside in reaching this determination, yet kept in mind in order to determine the “differences,” conduct the search and evaluate the “subject matter as a whole” of the invention. The tendency to resort to “hindsight” based upon applicant’s disclosure is often difficult to avoid due to the very nature of the examination process. However, impermissible hindsight must be avoided and the legal conclusion must be reached on the basis of the facts gleaned from the prior art.

ESTABLISHING A PRIMA FACIE CASE OF OBVIOUSNESS

**>The key to supporting any rejection under 35 U.S.C. 103 is the clear articulation of the reason(s) why the claimed invention would have been obvious. The Supreme Court in *KSR International Co. v. Teleflex Inc.*, 550 U.S. ___, ___, 82 USPQ2d 1385, 1396

(2007) noted that the analysis supporting a rejection under 35 U.S.C. 103 should be made explicit. The Federal Circuit has stated that "rejections on obviousness cannot be sustained with mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." *In re Kahn*, 441 F.3d 977, 988, 78 USPQ2d 1329, 1336 (Fed. Cir. 2006). See also *KSR*, 550 U.S. at ___, 82 USPQ2d at 1396 (quoting Federal Circuit statement with approval).<

If the examiner determines there is factual support for rejecting the claimed invention under 35 U.S.C. 103, the examiner must then consider any evidence supporting the patentability of the claimed invention, such as any evidence in the specification or any other evidence submitted by the applicant. The ultimate determination of patentability is based on the entire record, by a preponderance of evidence, with due consideration to the persuasiveness of any arguments and any secondary evidence. *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). The legal standard of "a preponderance of evidence" requires the evidence to be more convincing than the evidence which is offered in opposition to it. With regard to rejections under 35 U.S.C. 103, the examiner must provide evidence which as a whole shows that the legal determination sought to be proved (i.e., the reference teachings establish a *prima facie* case of obviousness) is more probable than not.

When an applicant submits evidence, whether in the specification as originally filed or in reply to a rejection, the examiner must reconsider the patentability of the claimed invention. The decision on patentability must be made based upon consideration of all the evidence, including the evidence submitted by the examiner and the evidence submitted by the applicant. A decision to make or maintain a rejection in the face of all the evidence must show that it was based on the totality of the evidence. Facts established by rebuttal evidence must be evaluated along with the facts on which the conclusion of obviousness was reached, not against the conclusion itself. *In re Eli Lilly & Co.*, 902 F.2d 943, 14 USPQ2d 1741 (Fed. Cir. 1990).

See *In re Piasecki*, 745 F.2d 1468, 223 USPQ 785 (Fed. Cir. 1984) for a discussion of the proper roles of the examiner's *prima facie* case and applicant's rebut-

tal evidence in the final determination of obviousness. See MPEP § 706.02(j) for a discussion of the proper contents of a rejection under 35 U.S.C. 103.

2143 >Examples of< Basic Requirements of a *Prima Facie* Case of Obviousness

**>The Supreme Court in *KSR International Co. v. Teleflex Inc.*, 550 U.S. ___, ___, 82 USPQ2d 1385, 1395-97 (2007) identified a number of rationales to support a conclusion of obviousness which are consistent with the proper "functional approach" to the determination of obviousness as laid down in *Graham*. The key to supporting any rejection under 35 U.S.C. 103 is the clear articulation of the reason(s) why the claimed invention would have been obvious. The Supreme Court in *KSR* noted that the analysis supporting a rejection under 35 U.S.C. 103 should be made explicit.

EXEMPLARY RATIONALES

Exemplary rationales that may support a conclusion of obviousness include:

- (A) Combining prior art elements according to known methods to yield predictable results;
- (B) Simple substitution of one known element for another to obtain predictable results;
- (C) Use of known technique to improve similar devices (methods, or products) in the same way;
- (D) Applying a known technique to a known device (method, or product) ready for improvement to yield predictable results;
- (E) "Obvious to try" – choosing from a finite number of identified, predictable solutions, with a reasonable expectation of success;
- (F) Known work in one field of endeavor may prompt variations of it for use in either the same field or a different one based on design incentives or other market forces if the variations are predictable to one of ordinary skill in the art;
- (G) Some teaching, suggestion, or motivation in the prior art that would have led one of ordinary skill to modify the prior art reference or to combine prior art reference teachings to arrive at the claimed invention.